



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Dale B. Schenk

Application No.: 09/724,953

Filed: November 28, 2000

For: PREVENTION AND TREATMENT
OF AMYLOIDOGENIC DISEASE

Examiner: Christopher J. Nichols

Art Unit: 1647

DECLARATION
UNDER 37 C.F.R. § 1.132 OF
MARTIN KOLLER, M.D., M.P.H.

RECEIVED

JUN 02 2003

TECH CENTER 1600/2900

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Martin Koller, M.D., M.P.H., state as follows.

(1) My current position is Vice President, Clinical Development – North America at Elan Pharmaceuticals, the parent company of Neuralab, Inc, which is the assignee of the above-captioned application. I have designed and conducted many clinical trials and have experience at interpreting the results of clinical trials. A copy of my curriculum vitae is attached.

(2) A phase I human clinical trial (Study AN1792(QS-21)-102, henceforth designated as Study 102), was conducted in which AN1792 (42 amino acid synthetic formulation of A β) plus the adjuvant QS-21 was administered to patients suffering from Alzheimer's disease (AD) in comparison to a placebo control group (adjuvant alone). Study 102 was an exploratory, randomized, multi-center, double-blind, multi-dose, dose-escalation, adjuvant-controlled, safety, tolerability and immunogenicity study in patients with mild to moderate AD in which up to 8 injections of study drug were administered to patients over 18 months. The study was designed to assess 4 dose groups of AN1792(QS-21) with 20 patients per group, randomized to active vs placebo in a 4 to 1 ratio resulting in a total of 64 active and 16 control patients within the study.

(3) The functional disability of patients in this trial was assessed before treatment with A β (baseline) and at intervals thereafter. The clinical outcome measure used to measure functional disability was the Disability Assessment for Dementia (DAD) scale. The

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considered
3/24/03